

Remarks

Claims 1-6, 8-14, 16-23 and 25-33 are pending in the subject application. By this Amendment, Applicants have canceled claims 32-33, amended claims 8 and 16 and added new claim 34. Support for the amendments and new claim can be found throughout the subject specification and in the claims as originally filed (see, for example, page 2, paragraph 1 and page 8, paragraph 1). Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 1-6, 8-14, 16-23, 25-31 and 34 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

Applicants gratefully acknowledge the Examiner's withdrawal of the rejection under 35 U.S.C. § 103(a) (over Wick *et al.*).

Claims 8 and 16 are objected to because of informalities. The Examiner indicates that the abbreviation "PFLA" should be "PLFA". Applicants gratefully acknowledge the Examiner's careful review of the claims. In accordance with the Examiner's suggestion, claims 8 and 16 have been amended to state the abbreviation as "PLFA". Accordingly, reconsideration and withdrawal of the objection is respectfully requested.

Applicants, again, request the courtesy of an interview to discuss the rejections of record at the time this response is considered.

Claims 31-33 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants respectfully assert that there is adequate written description in the subject specification to convey to the ordinarily skilled artisan that they had possession of the claimed invention. The Office Action argues that claims 31-33 constitute new matter in this application as it is argued that the specification does not provide support for the recitations of "isotope enriched substrate is an isotope enriched form of a contaminant present at the site", "isotope enriched substrate is a substrate that is more readily utilized by a bioremediation-capable microbial organism than by a bioremediation-incapable microbial organism" or "isotope enriched substrate by a bioremediation-capable microbial organism serves to facilitate bioremediation by said bioremediation-capable microbial organism". With respect to claims 32-33, Applicants submit that

the cancellation of the claims renders this issue moot. However, regarding claim 31, Applicants submit the as-filed specification clearly supports the recitation of “isotope enriched substrate is an isotope enriched form of a contaminant present at the site”. For example, the as-filed specification teaches, at page 5, lines 16-18, that “[a]dditionally, non-radioactive labeled (^{13}C) substrates or contaminants and/or surrogates may be added to the traps to stimulate a given response from the indigenous microbial community”. At page 8, lines 10-11, it is stated: [m]any refractory chemicals such as poly aromatic hydrocarbons, tars, asphaltenes, chorobenzenes or polychlorobiphenyls are utilized by very selective group of organisms. Such “refractory chemicals” are contaminants often found in contaminated groundwater sites (see, for example, De *et al.*, *Int. J. Hum. Genet.*, 2004, 4:281-290, Introduction, citing to various references published prior to the effective filing date of this application and Weiss *et al.*, *Groundwater Quality: remediation and Protection*, IAHS Publication No. 250, 1998, copies of which are attached). Applicants further note that Example 1 teaches that solid phase samples can be loaded with a labeled benzene substrate and lowered into a BTEX contaminated groundwater site. As noted in the Example, no significant exchange between the benzene loaded onto the solid support and benzene in the aquifer was noted. Applicants further submit that benzene is a well-known groundwater contaminant. Accordingly, Applicants respectfully submit that the as-filed specification provides adequate support for the phrase “isotope enriched substrate is an isotope enriched form of a contaminant present at the site” and reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, first paragraph, is respectfully requested.

Claims 1-6, 8-14, 16-18, 21-22 and 25-30 are rejected under 35 U.S.C. § 103(a) as obvious over Arao *et al.* (1999) in view of Peyton *et al.* (U.S. Patent No. 5,641,642) and Boschker *et al.* (1998). Applicants respectfully assert that the claimed invention is not obvious over the cited references.

The Office Action (at pages 6-7) indicates that Arao *et al.* “teaches contacting a community at a soil site with ^{13}C labeled acetate . . . [but] does not teach a method of contacting the microbial community in ground water with a sterile solid support that has be[en] loaded with the ^{13}C labeled acetate (step a) or incubating the solid support at the site for a period of time to establish a biofilm

(step b).” In an effort to cure these defects, the Office Action cites to Peyton *et al.* (U.S. Patent No. 5,641,642) and Boschker *et al.* (1998).

Peyton *et al.* is cited for its teachings of:

... a device which permits biofilm forming microorganism to adhere to packing material (e.g. solid support) in order to analyze the microorganisms at groundwater and subsurface sites (abstract and column 1 lines 15-25). Therefore Peyton *et al.* teaches a method wherein biofilms can be formed at the site of interest.

With regard to Claims 17-18 and 21-22, Peyton *et al.* teaches detection of microbes at groundwater or subsurface sites (column 1 lines 15-25).

With regard to Claims 25 and 28, Peyton *et al.* teaches that solid support comprises a perforated tube (Column 2 lines 10-11) which the acetate of Arao *et al.* would be loaded into in order to incorporate the 13C label into the sample.

With regard to Claims 26 and 29, Peyton *et al.* teaches that the tube comprises glass fibers or glass beads (column 2 lines 19-20).

With regard to Claims 27 and 30, Peyton *et al.* teaches incubating the tube for a period of time to establish a biofilm (abstract).

Boschker *et al.* is cited for its teachings of “a method of 13C labeling soil for PLFA analysis (p. 802 1st two paragraphs). Boschker *et al.* teaches that 13C can be directly injected into core samples from various sites of interest and that PLFA can be calculated (p. 804 1st column last paragraph). Therefore Boschker *et al.* teaches a method in which soil does not have to first be dried as in the method of Arao *et al.*, but rather soil can be directly incubated with 13C. Therefore Boschker *et al.* indicates direct detection can be performed rather than detection only after drying a sample. However, Boschker *et al.* does not teach that this direct detection can be performed on site.”

As noted in the previous response, all the claim limitations must be taught or suggested by the prior art in order to establish the *prima facie* obviousness of a claimed invention (*CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) citing *In re Royka*, 490 F.2d 981, 985 (C.C.P.A. 1974)). In this case, each of the limitations of claim 1 is not taught or suggested by the cited combination of references. Particularly, there is no teaching or suggestion that the substrates contained within the device of Peyton *et al.* could, or should, be loaded with a labeled substrate upon which a biofilm could form and such a suggestion could not be gleaned from the teachings of either Arao *et al.* or Boschker *et al.* As noted in the Office Action, these references teach the direct injection of 13C acetate into a soil sample/core (Boschker *et al.*) or the addition of 13C acetate to soil

samples that are then dried (Arao *et al.*). Neither reference teaches or suggests that one skilled in the art should load a non-radioactively labeled substrate onto a packing material as taught in Peyton *et al.*

Indeed, Peyton *et al.* appear to specifically discourage the use of a substrate on the packing material or coupon disclosed within the teachings of the cited patent. As noted in the first paragraph of the Introduction,

Through a number of different methods, the groundwater has been contaminated in many areas with a variety of noxious chemicals. While there are chemical methods available to remediate such pollution, a technique known as "in-situ bio-remediation" may be preferred in many cases. For example, if a population of microbial organisms capable of remediating a particular chemical pollutant either already exists *in situ* or can be introduced to the subsurface zone requiring remediation, introducing excess nutrients to the microbial population to stimulate growth and biological activity can greatly enhance bio-remediation. However, before such bio-remediation can occur, a census of microbial growth must be accurately known in order to provide optimal nutrients for growth of the desired organisms.

Thus, it is clear that the device of Peyton *et al.* is to be used without the loading of a substrate on the packing material in order to obtain an accurate census of the population of microorganisms (*i.e.*, to avoid enriching for a particular subpopulation of microorganisms). This is further suggested by the Example which states:

Glass wool having approximately 10 μ m diameter strands was firmly packed into a 7" cylindrical sampling coupon constructed of 304 stainless steel, with 12 grids/inch. The total glass wool weight was 1.15 g and the total volume available within the sampling coupon was 12.6 mL, yielding a packed density of 0.091 g/mL. The packed coupon was autoclaved and placed in sampling wells for 12 and 22 days. Total and denitrifying viable cells were enumerated using both denitrifying MPN broth and PTYG plate counts. The remaining portion of the glass wool was frozen for molecular probe analysis.

As noted previously, one of skill in the art would understand that introducing excess nutrients on the sampler *during* the census would tend to alter the size and/or composition of the microbial community that localizes to the device of Peyton *et al.*, thus rendering the census inaccurate; however, the claimed invention of this application requires that the solid support be loaded or coated

with an isotope enriched substrate. One of ordinary skill would understand that this requirement of the claimed invention is thus incompatible with the purpose of *Peyton et al.* and, as the Patent Office is aware, if a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 U.S.P.Q. 1125 (Fed. Cir. 1984). Thus, one of ordinary skill in the art would not have been motivated to utilize the sampler of *Peyton et al.* for the purposes urged in the Office Action.

In responding to the previous response in this matter, the Office Action argues that one cannot show nonobviousness by attacking references individually where the rejections are based upon combinations of references. However, it is also fundamental patent law that an obviousness rejection fails if the prior art relied on does not disclose all of the limitations of the claimed invention. *See, e.g., In re Zurko*, 258 F.3d 1379, 1385-86 (Fed. Cir. 2001). Thus, obviousness requires a teaching or suggestion of all limitations in a claim. *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (citing *In re Royka*, 490 F.2d 981, 985 (C.C.P.A. 1974)). Furthermore, as the Supreme Court stated, “*there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.*” *KSR Int’l v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (emphasis added)).

In this case, the references have not been attacked individually; rather, Applicants have pointed out how a *prima facie* case of obviousness has not been established because the cited references fail to disclose, teach or suggest all of the limitations of the claimed invention. For example, *Boschker et al.* and *Arao et al.* teach the injection or addition of ¹³C containing acetate into soil sample, a step that is not related to claims of this matter. *Peyton et al.*, cited for the purposes of showing a device similar to that claimed herein, expressly utilizes sterile packing material that does not contain substrate upon which microorganisms can grow in order to obtain an accurate census of the microorganisms at a particular subsurface site (see Example and previously cited sections of the reference). Thus, it is clear that the cited combination of references fails to teach each of the limitations of the claimed invention (*e.g.*, contacting a microbial community at a subsurface site or down-well groundwater site with a sterilized solid support loaded or coated with an isotope enriched substrate), particularly since the modification of *Peyton et al.* urged in the Office

Action would have rendered the device unsuitable for its intended purpose of obtaining an accurate census of the microbial population at a particular subsurface site. As noted previously, if a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 U.S.P.Q. 1125 (Fed. Cir. 1984).

Applicants further note that the Office Action, at page 11, states that it would have been obvious to one of ordinary skill in the art that a solid support with 13C could be used to create a biofilm as taught by Arao *et al.* at the site as taught by Peyton *et al.* in order to determine the *in situ* changes in soil bacterial and functional activities. Peyton *et al.* further teach that the system can measure the accumulation rate of the bioremediation process (column 1, lines 60-63), as such, the reference teaches that a census can be taken not only without the introduction of excess nutrients but also in the presence of excess nutrients. In this regard, Applicants submit that there is no teaching of a biofilm in Arao *et al.*, the reference is directed to measuring the activity of soil bacteria. Regarding the purported teachings of Peyton *et al.*, the cited passage states: "In addition, there is a need for a system to measure the accumulation rate of the in-situ biofilm formation during the active bioremediation process, and to determine the effects of in-situ biomass transport processes such as cellular attachment and detachment." It is unclear how the Patent Office extends these teachings to the reference teaching that "a census can be taken not only without the introduction of excess nutrients but also in the presence of excess nutrients", particularly since the reference teaches the use of sterile packing material that is not coated with a substrate of any kind in order to obtain an accurate census of a microbial population at a subsurface site. As the Supreme Court stated, "there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR Int'l v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)). In this case, no such articulated reasoning and rational underpinning has been provided and it is respectfully submitted that a *prima facie* case of obviousness has not been established. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a) is respectfully requested.

Claims 19 and 23 are rejected under 35 U.S.C. § 103(a) as obvious over Arao *et al.* in view of Peyton *et al.* and Boschker *et al.* and in further view of Alexandrino *et al.* As noted above, Arao *et*

al. and Boschker *et al.* do not teach a method adapted for *in situ* use at a subsurface site or a down-well groundwater site and the references also fail to teach or suggest coating or loading a solid support with an isotope enriched substrate. As also noted above, Peyton *et al.* fail to teach coating or loading a solid support with an isotope enriched substrate and Applicants submit that doing so would have rendered the device of Peyton *et al.* unsuitable for its intended purpose. Applicants also note that while Alexandrino *et al.* may perhaps teach the use of ^2H , Alexandrino *et al.* fail to cure the deficiencies of Arao *et al.*, Boschker *et al.*, and Peyton *et al.* as set forth above. Applicants, thus, respectfully assert that the claimed invention is not obvious over the cited references because each of the limitations of the claimed invention have not been taught and reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a) is respectfully requested.

Claims 20 and 23 are rejected under 35 U.S.C. § 103(a) as obvious over Arao *et al.* (1999) in view of Boschker *et al.* and Peyton *et al.* and in further view of Kharlamenko *et al.* (2001). The defects in the teachings of Arao *et al.* and Boschker *et al.* have been discussed above. As also noted above, Peyton *et al.* fail to teach coating or loading a solid support with an isotope enriched substrate and doing so would have rendered the device of Peyton *et al.* unsuitable for its intended purpose. Finally, while Kharlamenko *et al.* may perhaps teach the use of ^{34}S , Kharlamenko *et al.* cannot cure the deficiencies noted with respect to the teachings of Arao *et al.*, Boschker *et al.*, and Peyton *et al.* as set forth above. Applicants thus respectfully assert that the claimed invention is not obvious over the cited references and reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a) is respectfully requested.

Claims 31-33 are rejected under 35 U.S.C. § 103(a) as obvious over Arao *et al.* (1999), Peyton *et al.* (U.S. Patent No. 5,641,642), Boschker *et al.* (1998) and in view of Lytle *et al.* (2001). Applicants respectfully assert that the claimed invention is not obvious over the cited references. As noted above, Arao *et al.* and Boschker *et al.* do not teach a method adapted for *in situ* use at a subsurface site or a down-well groundwater site and the references also fail to teach or suggest coating or loading a solid support with an isotope enriched substrate. As also noted above, Peyton *et al.* fail to teach coating or loading a solid support with an isotope enriched substrate and that doing so would have rendered the device of Peyton *et al.* unsuitable for its intended purpose. The Office Action argues that Lytle *et al.* teach a method of using ^{13}C labeled bacteria as tracers for

bioremediation and that Lytle *et al.* teach that 13C is a form of the contamination present at the site. Regarding the assertion that Lytle *et al.* teach that 13C is a form of the contamination present at the site, Applicants respectfully request the Examiner to identify those portions of Lytle *et al.* supporting this assertion. Applicants note that bacterial cells labeled with 13C were introduced into sediment cores (see page 273, 2.2.1) and that Lytle *et al.* indicate that microbial cells grown to saturation in 13C can be used as a specific tracer of that microbial cell in subsurface sediments (paragraph bridging pages 279-280). Such teachings, however, fail to remedy the defects noted with regard to the teachings of Arao *et al.*, Peyton *et al.* and Boschker *et al.* Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a) is respectfully requested because a *prima facie* case of obviousness has not been established.

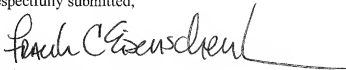
It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicants' agreement with or acquiescence in the Examiner's position. Applicants expressly reserve the right to pursue the invention(s) disclosed in the subject application, including any subject matter canceled or not pursued during prosecution of the subject application, in a related application.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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Attachments: Copy of De *et al.*, 2004

Copy of Weiss *et al.*, 1998